

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0327]

DMB

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Certifier D. Hawkins

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits public comment on the reporting requirements for sponsors electronically requesting meetings or teleconferences with the Center for Veterinary Medicine's (CVM), Office of New Animal Drug Evaluation (ONADE).

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD

20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. Collection of information is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on How to Use E-Mail to Submit a Request for a Meeting or Teleconference to the Office of New Animal Drug Evaluation—21 CFR Part 511 (OMB Control Number 0910-0452)—Extension

“Any person intending to file a new animal drug application or abbreviated application is entitled to request meetings and/or teleconferences to reach agreement regarding a submission or investigational requirement (21 U.S.C. 360b(b)(3)). Every person outside the Federal Government may request a meeting with representative(s) of FDA to discuss a matter (21 CFR 10.65(c))”.

Sponsors often meet with CVM scientists in CVM’s Office of New Animal Drug Evaluation to formulate a rational approach to studies to be conducted and to discuss how to meet the statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Requests for meetings and teleconferences about NAD submissions are currently submitted on paper to CVM.

This guidance document describes the procedure for persons to submit a request for a meeting or teleconference electronically on FDA Form No. 3489. The information sponsors should include on the form includes the sponsor’s name and address, a list of agency participants, an agenda, and notification of audiovisual equipment that will be needed. The form has been updated to allow sponsors to indicate whether the request amends a previous request for a meeting and to allow for consistency across forms. The likely respondents to this collection of information are new animal drug sponsors.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

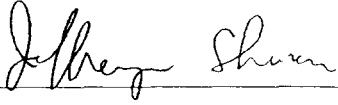
Form No	No of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
FDA Form 3489	12	14	168	0 69	116

¹ There are no capital costs or operating and maintenance costs associated with this collection of information

The estimates in table 1 of this document resulted from discussions with new animal drug sponsors. The estimated burden includes requests for meetings or teleconferences submitted by e-mail and on paper.

JUL 30 2003

Dated: _____
July 30, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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